

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

Astellas Institute for Regenerative Medicine, and
Stem Cell & Regenerative Medicine
International, Inc.,

Plaintiffs,

v.

ImStem Biotechnology, Inc.,
Xiaofang Wang, and
Ren-He Xu,

Defendants.

Civil Action No. 1:17-cv-12239

Hon. Allison D. Burroughs

**PLAINTIFFS ASTELLAS' AND SCRMI'S MEMORANDUM IN SUPPORT OF
THEIR MOTION TO DISMISS DEFENDANTS
IMSTEM'S AND XIAOFANG WANG'S COUNTERCLAIMS**

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TABLE OF ABBREVIATIONS

'321 patent	U.S. Patent No. 8,962,321 to Kimbrel, et al.
'551 patent	U.S. Patent No. 9,745,551 to Wang, et al.
'956 patent	U.S. Patent No. 8,961,956 to Kimbrel, et al.
Astellas	Astellas Institute for Regenerative Medicine
BM-MSC	Bone Marrow Mesenchymal Stem (or Stromal) Cell
Defendants	ImStem and Dr. Xiaofang Wang
EAE	Experimental Autoimmune Encephalomyelitis
ESC	Embryonic Stem Cell
GvHD	Graft-Versus-Host Disease
hESC	Human Embryonic Stem Cell
ImStem	ImStem Biotechnology, Inc.
MS	Multiple Sclerosis
MSC	Mesenchymal Stem (or Stromal) Cell
NOA	U.S. Appl. No. 13/905,526, Notice of Allowance (Dec. 17, 2014) (application issued as '956 patent)
Plaintiffs	Astellas and SCRMI
SCRMI	Stem Cell & Regenerative Medicine International, Inc.
UCB-MSC	Umbilical-Cord-Blood MSC

All emphasis added unless otherwise indicated.

I. INTRODUCTION

This Court should dismiss ImStem Biotechnology, Inc. (“ImStem”) and Xiaofang Wang’s (collectively, “Defendants”) Counterclaims against Astellas Institute for Regenerative Medicine (“Astellas”) and Stem Cell & Regenerative Medicine International, Inc. (“SCRMI”) (collectively “Plaintiffs”) because, even accepting their allegations as true (solely for the purposes of this motion), Dr. Wang contributed nothing more to the patented invention than was already well known in the field. Defendants cannot succeed with a claim for correction of inventorship by alleging that they contributed ideas that were known in the prior art. *See Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004).

The true inventors of U.S. Patent No. 8,961,956 (“the ’956 patent”) developed a novel method of generating a specific type of stem cell (called mesenchymal stem cells (“MSCs”)). Such MSCs were understood to be potentially useful in treating a wide range of diseases. By Defendants’ own admissions and assertions, Dr. Wang purportedly made only two contributions to this invention: (1) he suggested the inventors study the effectiveness of using their MSCs to treat autoimmune disease, specifically by conducting experiments in a mouse model of multiple sclerosis; and (2) he conducted those mouse studies. But both of those alleged contributions were well-known and well-documented in the prior art. The ’956 patent itself incorporates several prior art scientific articles describing use of MSCs, made by previously-known methods, in mouse models of autoimmune diseases, including multiple sclerosis (“MS”), and including the specific mouse model Dr. Wang alleges he contributed to the invention. In essence, Dr. Wang’s alleged suggestion was merely to use and test the MSCs in the same way scientists in the field had already been using and testing such cells.

As a matter of law, Dr. Wang cannot be a co-inventor on the ’956 patent. Because

inventorship is a legal issue and Dr. Wang's alleged role in the invention (accepting Defendants' allegations as true for the purposes of this motion) does not qualify as an inventive contribution, and does not state a plausible grounds for relief. This Court should dismiss Defendants' counterclaims with prejudice.

II. FACTUAL BACKGROUND

A. Drs. Kimbrel and Lanza Invented The Method For Making MSCs Using A Hemangioblast Intermediate

MSCs are stem cells, capable of self-renewal and having the ability to differentiate into different types of cells, such as bone, fat, or cartilage. '956 patent, 1:53-56; (D.I. 20, at Countercl. ¶ 12). Prior to the invention of the '956 patent, scientists derived MSCs directly from embryonic stem cells ("ESCs") or from adult stem cells found in bone marrow, peripheral blood, or adipose tissue. U.S. Appl. No. 13/905,526, Notice of Allowance, at 2-3 (Dec. 17, 2014) [hereinafter NOA] (application 13/905,526 issued as the '956 patent on February 24, 2015) [Ex. A]. But these known derivation methods had significant drawbacks—adult-tissue-derived MSCs did not grow and divide (proliferate) or become other cell types (differentiate) as well, and the methods for directly deriving MSCs from ESCs produced low quantities of cells of inconsistent quality and characteristics. '956 patent, 2:5-42; (*see also* D.I. 1-2, at 2).

Despite the limitations of the then-known methods to generate MSCs, the MSCs were known to have important qualities, such as the ability to modulate the immune system. These qualities indicated their potential utility for treating a range of conditions. '956 patent, 1:56-60; (*see also, e.g.*, D.I. 20, at Countercl. ¶ 14; D.I. 1-2, at 2 (citing scientific papers)). For example, clinical studies at the time were investigating whether MSCs could be used to treat graft-versus-host disease ("GvHD"), myocardial infarction, and autoimmune diseases. '956 patent, 1:56-67. Nevertheless, a problem remained: these treatment regimens require large numbers of MSCs

(potentially several million MSCs per kilogram of a patient), but obtaining these large numbers of quality MSCs using the known methods of deriving them was difficult.

Drs. Erin Kimbrel and Robert Lanza solved this problem by inventing a new method for obtaining substantial numbers of high quality MSCs from ESCs. (*See, e.g.*, D.I. 20, at Ans. ¶ 3.) First, Drs. Kimbrel and Lanza differentiated ESCs into a special type of cell called a hemangioblast. Hemangioblasts are pluripotent cells (i.e., they can be derived into many, but not all, cell types) and are thought to be a transitional cell that occurs during ordinary embryonic development. '956 patent, 21:19-29; NOA at 3. Second, Drs. Kimbrel and Lanza differentiated their hemangioblasts into MSCs. *See, e.g.*, '956 patent, Abstract, Claim 1; NOA at 3. This inventive method, involving the use of a hemangioblast intermediate, produced large numbers of MSCs with the characteristics of youthful cells.¹ '956 patent, 2:46-52.

Having devised a new way of making MSCs, the inventors sought to characterize them and evaluate their properties in models for diseases, including those in which MSCs had previously been tested. *See, e.g.*, '956 patent, 49:40-84:9 (Examples 2-23); (*see also, e.g.*, D.I. 1-2; D.I. 1-4). While Drs. Kimbrel and Lanza did much of the characterization work with their colleagues at Astellas and SCRMI, they sought collaborators to test their inventive MSCs. The patent reports the outcome of these collaborations, involving four different mouse models of human diseases. Specifically, the examples of the '956 patent describe results from studies in mouse models of pain ('956 patent, 65:1-66:32), multiple sclerosis (Experimental Autoimmune Encephalomyelitis or “EAE”) ('956 patent, 51:30-53:60, 67:50-83:49), uveitis ('956 patent, 66:33-67:49), and lupus ('956 patent, 83:50-84:9).

¹ The role of co-inventors Jianlin Chu and Nicholas Arthur Kouris is not relevant to ImStem’s and Dr. Wang’s counterclaims, and as such is not recounted here.

B. Drs. Kimbrel And Lanza Collaborated With Dr. Wang To Test MSCs In A Known Animal Model Of Multiple Sclerosis

As Defendants ImStem and Dr. Wang admit, Drs. Kimbrel and Lanza first developed their inventive method for making MSCs, then provided their MSCs to various collaborators for testing in animal models of disease. (*See, e.g.*, D.I. 20, at Ans. ¶ 4 (admitting “Drs. Kimbrel and Lanza sought out collaborators who could test their cells in different animal models of relevant diseases”); D.I. 1-2 (paper published as results of those collaborations); D.I. 1-4 (same).) Dr. Wang, one such collaborator, took both Dr. Kimbrel’s protocol for differentiating hemangioblasts into MSCs as well as MSCs made by Dr. Kimbrel to test in the EAE model of multiple sclerosis. (D.I. 20, at Ans. ¶ 35.)

As Defendants ImStem and Dr. Wang further admit, the published article arising from the collaboration between Drs. Kimbrel, Lanza, Wang, and Dr. Ren-He Xu did not suggest that Dr. Wang had a role in the methods for making MSCs, instead attributing their production to an earlier article co-authored by Drs. Kimbrel and Lanza, but not Dr. Wang. (D.I. 20, at Ans. ¶ 44 (admitting the allegations in Compl. ¶ 44); *see also* D.I. 1-4 (the Kimbrel et al., 2014 article referenced in Compl. ¶ 44).)

ImStem’s and Dr. Wang’s counterclaims arise out of their allegation that “Dr. Wang suggested that the parties study MSC’s functionality in treating autoimmune disorders, including multiple sclerosis.” (D.I. 20, at Countercl. ¶ 2.) And that Dr. Wang “conducted all of the *in vivo* animal studies for the MSC collaboration” and “shared his resulting data with plaintiffs.” (*Id.* at Countercl. ¶ 2; *see also*, *e.g.*, *id.* at Countercl. ¶ 40.) Specifically, Defendants allege that Dr. Wang suggested that the parties’ “collaboration focus on testing the effectiveness of MSCs to treat autoimmune disease,” (*id.* ¶ 18; *see also* *id.* at Countercl. ¶¶ 2, 33, 34), that “they use the EAE mouse model to test the MSC’s functionality to treat multiple sclerosis,” (*id.* at Countercl.

¶ 18), and that “Dr. Wang conducted *in vivo* experiments on the EAE model” and “[a]t various times, Dr. Wang sent the resulting data to Dr. Kimbrel,” (*id.* at Countercl. ¶ 24, *see also id.* at Countercl. ¶¶ 2, 40, 48). Notably, these are the *only* contributions that Defendants allege Dr. Wang made to the invention of the ’956 patent.

C. The Invention Of U.S. Patent No. 8,961,956

The ’956 patent “relates to novel preparations of [MSCs] derived from hemangioblasts, methods for obtaining such MSCs, and methods of treating a pathology using such MSCs.” ’956 patent, Abstract. In a related patent, the same inventors claimed the method of producing MSCs through hemangioblast intermediates. *See, e.g.*, U.S. Patent No. 8,962,321 (“the ’321 patent”). And the claims of the ’956 patent focus on methods of using those novel MSCs to treat a disease or disorder. ’956 patent, Claim 1. When allowing the ’956 patent’s application, the Examiner reasoned:

As the hemangioblast-derived MSCs are found to be an allowable product, the methods of use of said products are also deemed free of the art. Furthermore, within the instant application Applicants have shown examples of therapeutic methods where the hemangioblast-derived MSCs are successfully used. Given the fact that the hemangioblast-derived MSCs have the same general properties as naturally occurring MSCs, it is reasonable to conclude that the hemangioblast-derived MSCs may be successfully used in all therapeutic application in which naturally occurring (i.e. bone marrow-derived MSCs) can be used.

NOA at 3.²

Consistent with the Examiner’s finding, the inventors claimed that the hemangioblast-

² When considering a motion to dismiss, the Court considers not only the counterclaim pleading, “but also matters fairly incorporated within it and matters susceptible to judicial notice,” and courts “may look to matters of public record in deciding a Rule 12(b)(6) motion.” *In re Colonial Mortg. Bankers Corp.*, 324 F.3d 12, 15-16 (1st Cir. 2003). The file history of a patent is a public record which can be accessed via the U.S. Patent and Trademark Office’s website. *See* <https://portal.uspto.gov/pair/PublicPair>.

derived MSCs have a broad range of therapeutic applications. Claim 1 of the '956 patent, the only independent claim, discloses:

A method for treating a disease or disorder, comprising administering to a subject in need thereof an effective amount of mesenchymal stromal cells or a preparation of mesenchymal stromal cells obtained by a method comprising culturing hemangioblasts under conditions that give rise to mesenchymal stromal cells.

'956 patent, Claim 1.

Defendants point to two claims pertaining to Dr. Wang's purported contributions. (D.I. 20, at Countercl. ¶ 28.) These claims identify a laundry list of over 60 diseases and disorders that can benefit from treatment with MSCs—including multiple sclerosis. Claim 3 recites:

The method of claim 1, wherein the disease or disorder is selected from ***multiple sclerosis***, systemic sclerosis, hematological malignancies, myocardial infarction, organ transplantation rejection, chronic allograft nephropathy, cirrhosis, liver failure, heart failure, GvHD, . . . Crohn's disease, diabetes, . . . amyotrophic lateral sclerosis, . . . refractory systemic lupus erythematosus, . . . lupus nephritis, . . . arthritis, bone regeneration, inflammatory respiratory conditions, . . . hearing loss, autoimmune hearing loss, noise-induced hearing loss, psoriasis or any combination thereof.

'956 patent, Claim 3. And claim 4 recites:

The method of claim 1, wherein the disease or disorder is uveitis, ***an autoimmune disorder***, an immune reaction against allogenic cells, ***multiple sclerosis***, bone loss, cartilage damage, or lupus.

'956 patent, Claim 4.

III. LEGAL STANDARDS

A. Motion To Dismiss For Failure To State A Claim

First Circuit procedural law applies to this motion to dismiss under Rule 12(b)(6), *Merck & Co. v. Hi-Tech Pharmcal Co.*, 482 F.3d 1317, 1320 (Fed. Cir. 2007), such that this Court must “take[e] as true the well-pleaded facts contained in the [counterclaim] and draw[] all reasonable

inferences therefrom in the [Defendants'] favor." *Garrett v. Tandy Corp.*, 295 F.3d 94, 97 (1st Cir. 2002).

A counterclaim must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To satisfy this requirement, a counterclaim "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Epoxy Tech., Inc. v. Daizo Corp.*, No. 12-11409-RWZ, 2013 WL 2146844, at *1 (D. Mass. May 16, 2013) (*Iqbal* and *Twombly* pleading standard applies to counterclaims); *PetEdge, Inc. v. Marketfleet Sourcing, Inc.*, No. 16-12562-FDS, 2017 WL 2983086, at *1 (D. Mass. July 12, 2017) (same). To survive a motion to dismiss, a counterclaim's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555-56 (citations omitted).

B. Inventorship

Inventorship is a question of law. *Abbott Biotechnology Ltd. v. Centocor Ortho Biotech, Inc.*, 35 F. Supp. 3d 163, 171 (D. Mass. 2014) (citing *Nartron Corp. v. Schukra U.S.A. Inc.*, 558 F.3d 1352, 1356 (Fed. Cir. 2009)). "[A] person is a joint inventor only if he contributes to the conception of the claimed invention." *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004).

To be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention. This requires more than merely exercising ordinary skill in the art—a person will not be a co-inventor if he or she does no more than explain to the real inventors concepts that are well known in the current state of the art.

Caterpillar Inc., 387 F.3d at 1377 (alterations and citations omitted). As a question of law, it is

appropriate to resolve inventorship disputes based on the pleadings. *See Coda Dev. s.r.o. v. Goodyear Tire & Rubber Co.*, No. 5:15-cv-1572, 2016 WL 5463058 (N.D. Ohio Sept. 29, 2016); *see also FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1097 (Fed. Cir. 2016) (affirming dismissal under Rule 12(b)(6) where court resolved an issue of law (patent eligibility under 35 U.S.C. § 101)).

C. Unjust Enrichment

To succeed with a claim for unjust enrichment, a party must show: “First, a benefit or enrichment was conferred upon the defendant; second, the retention of that benefit or enrichment resulted in a detriment to the plaintiff; and, third, there are circumstances which make the retention of that benefit unjust.” *Max-Planck-Gesellschaft zur Foerderung der Wissenschaften E.V. v. Whitehead Inst. for Biomedical Research*, 850 F. Supp. 2d 317, 333 (D. Mass. 2011) (alterations and citations omitted).

IV. ARGUMENT

Even assuming for the purposes of this motion that Defendants’ allegations of Dr. Wang’s contributions to the ’956 patent are true, such contributions are legally insufficient to qualify Dr. Wang as a co-inventor. The ’956 patent is directed to using MSCs made via a specific methodology (involving a hemangioblast intermediate) to treat diseases or disorders. ’956 patent, Claim 1; *see also id.* at Abstract (patent relates to “novel preparations of [MSCs] derived from hemangioblasts . . . and methods of treating a pathology using such MSCs”). Dr. Wang claims he made two overlapping contributions to the ’956 patent: (1) he suggested the inventors study “the effectiveness of MSCs to treat autoimmune disease”—specifically “us[ing] the EAE mouse model to test [Drs. Kimbrel’s and Lanza’s] MSC’s functionality to treat multiple sclerosis,” (D.I. 20, at Countercl. ¶ 18); and (2) Dr. Wang “conducted all of the *in vivo* animal studies for the MSC collaboration and shared his resulting data with plaintiffs,” (*id.* at

Countercl. ¶ 2; *see also id.* at Countercl. ¶¶ 24, 40). The contributions he allegedly made are well-documented in the prior art and do not rise to the level of an inventive contribution. *See Gen. Elec. Co. v. Wilkins*, 750 F.3d 1324, 1332 (Fed. Cir. 2014) (finding defendant “contributed nothing beyond what was already known in the art,” and as such should not be named as a co-inventor). And because Defendants’ unfair competition allegations are premised on Dr. Wang’s claim of co-inventorship, the unfair competition claim should likewise be dismissed.

A. None of Dr. Wang’s Contributions Qualify Him As An Inventor

Dr. Wang cannot be a co-inventor on the ’956 patent because his only purported contributions were well-known in the prior art. While Astellas and SCRMI disagree with a number of Dr. Wang’s assertions,³ even accepting ImStem’s and Dr. Wang’s allegations as true, solely for purposes of this motion, Dr. Wang is not a co-inventor under controlling law.

1. It was well known that MSCs might be effective in treating autoimmune diseases such as multiple sclerosis

Dr. Wang contends he suggested to Drs. Kimbrel and Lanza that they evaluate whether their hemangioblast-derived MSCs could treat autoimmune diseases, including MS, and suggested use of the EAE model. But that merely explains concepts well-known at the time—that MSCs might be useful to treat MS, and that MSCs could be tested in the EAE model. Inventors “may consult with others in the course of development without rendering each consultant a co-inventor.” *Abbott Biotechnology Ltd.*, 35 F. Supp. 3d at 171 (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 111 (1853)). Thus, these alleged contributions do not qualify him as a co-inventor.

³ For example, Drs. Kimbrel and Lanza were aware that MSCs had potential as a treatment for autoimmune conditions and were aware of the EAE model generally. Dr. Wang did not introduce these concepts to the inventors. Likewise, Astellas disagrees that it was Dr. Wang who first suggested testing their MSCs in autoimmune models.

As the '956 patent explains, in years leading up to the patent “intense research on the . . . properties of human MSC has indicated that these cells can be used to treat a range of clinical conditions, including immunological disorders as well as degenerative diseases.” '956 patent, 1:56-61. Moreover, at that time “the number of clinical studies with MSC ha[d] been steadily increasing for a wide variety of conditions [including] . . . autoimmune diseases and disorders.” *Id.* at 1:61-65. The specification likewise refers to a number of studies reporting testing MSCs as a cellular therapy for multiple sclerosis. *E.g.*, '956 patent, 81:6-11, 81:58-62, 83:35-39 (citing Karussis 2010, Mohyeddin Bonab 2007, and Yamout 2010⁴). Indeed, the article reporting the results of the parties’ collaboration⁵ cites some of the same articles for the proposition that “[h]uman adult-tissue-derived MSCs have shown therapeutic utility in . . . clinical trials for MS patients.” (D.I. 1-2 at 2 (citing, *e.g.*, Karussis 2010, Mohyeddin Bonab 2007, and Yamout 2010).) Because these concepts—identical to what Dr. Wang purportedly contributed—are identified in the specification as prior art, it is appropriate to dismiss the claim for correction of inventorship. *See Coda Dev. s.r.o.*, 2016 WL 5463058, at *5-6.

The '956 patent also explains that MSCs derived from various, non-hemangioblast, sources have been used in precisely the EAE model that Dr. Wang purports to have suggested. Specifically, the patent reports that such cells were “used for EAE treatment and ha[d] been

⁴ D. Karussis et al., *Safety and immunological effects of mesenchymal stem cell transplantation in patients with multiple sclerosis and amyotrophic lateral sclerosis*. 67 Arch. Neurol. 1187-94 (2010) (“Karussis 2010”); M. Mohyeddin Bonab et al., *Does mesenchymal stem cell therapy help multiple sclerosis patients? Report of a pilot study*. 4 Iranian J. of Immunology 50-57 (2007) (“Mohyeddin Bonab 2007”); B. Yamout et al., *Bone marrow mesenchymal stem cell transplantation in patients with multiple sclerosis: a pilot study*. 227 J. Neuroimmunol. 185-89 (2010) (“Yamout 2010”).

⁵ X. Wang et al., *Human ESC-Derived MSCs Outperform Bone Marrow MSCs in the Treatment of an EAE Model of Multiple Sclerosis*, 3 Stem Cell Reports 115-30 (2014) (D.I. 1-2).

thoroughly studied” prior to the invention of the ’956 patent. *E.g.*, ’956 patent, 52:4-15, 84:13-15, 85:10-12 (discussing use of mouse BM-MSCs and umbilical-cord-blood-MSCs (“UCB-MSCs”) in the EAE model and citing Zappia 2005 and Liang 2009⁶) Example 22 of the ’956 patent reports that the hemangioblast-derived MSCs used in its EAE studies had similar cellular markers as the mouse BM-MSCs used in an earlier EAE study. *See* ’956 patent at 74:10-11 (citing Zappia 2005). And the article reporting the parties’ EAE study results lists even more articles where “[h]uman adult-tissue derived MSCs have shown therapeutic utility in experimental autoimmune encephalitis (EAE) models of MS (Bai et al., 2009; Gordon et al., 2008, 2010; Peron et al., 2012; Zhang et al., 2005⁷).” (D.I. 1-2 at 2.)

Dr. Wang’s admissions that the idea of using MSCs to treat MS was in the prior art defeat any plausible claim of co-inventorship. *See Nartron Corp.*, 558 F.3d at 1355 (purported inventor admitted that the idea he contributed to the invention was in the prior art). In their Answer, Defendants admitted that the EAE model was a commonly used animal model for multiple sclerosis. (D.I. 20, at Ans. ¶ 4.) Dr. Wang also explained in the Background section of the ’551

⁶ E. Zappia et al., *Mesenchymal Stem Cells Ameliorate Experimental Autoimmune Encephalomyelitis Inducing T-cell Anergy*, 106 Blood 1755-61 (2005) (“Zappia 2005”); J. Liang et al., *Allogeneic Mesenchymal Stem Cells Transplantation in Treatment of Multiple Sclerosis*, 15 Multiple Sclerosis 644-46 (2009) (“Liang 2009”).

⁷ L. Bai et al., *Human bone marrow-derived mesenchymal stem cells induce Th2-polarized immune response and promote endogenous repair in animal models of multiple sclerosis*, 57 Glia 1192-1203 (2009); D. Gordon et al., *Human mesenchymal stem cells abrogate experimental allergic encephalomyelitis after intraperitoneal injection, and with sparse CNS infiltration*, 448 Neurosci. Lett. 71-73 (2008); D. Gordon et al., *Human mesenchymal stem cells infiltrate the spinal cord, reduce demyelination, and localize to white matter lesions in experimental autoimmune encephalomyelitis*, 69 J. Neuropathol. Exp. Neurol. 1087-95 (2010); J.P. Peron et al., *Human endometrial-derived mesenchymal stem cells suppress inflammation in the central nervous system of EAE mice*, 8 Stem Cell Rev. 940-52 (2012); J. Zhang et al., *Human bone marrow stromal cell treatment improves neurological functional recovery in EAE mice*, 195 Exp. Neurol. 16-26 (2005).

patent, which is the subject of Plaintiffs' inventorship claim, that MSCs had “been found efficacious in the treatment of mice with experimental autoimmune encephalomyelitis (EAE), a well-recognized animal model of MS.” (D.I. 1-1, at 37 ('551 patent, 2:26-33 (citing, *inter alia*, Zappia 2005 and other articles from 2008 and 2010)).) And this section also recognizes that MSCs had already been used in clinical trials of MS, citing some of the same references as in the '956 patent. *Id.* (citing, *inter alia*, Karussis 2010, Mohyeddin Bonab 2007, and Yamout 2010); *see* '956 patent, 81:6-11, 81:58-62, 83:35-39 (citing same).

There is nothing novel or inventive about the idea of testing MSCs in the EAE model or for using MSCs to treat MS—at best, Dr. Wang merely informed the inventors about a well-documented tool for testing the therapeutic potential of their cells. This is legally insufficient to support Dr. Wang’s claim for co-inventorship. *See Caterpillar Inc.*, 387 F.3d at 1378 (noting “various publicly available texts and patents described” the contribution of the purported co-inventor); *Ruling Meng v. Ching-Wu Chu*, 643 F. App’x 990, 996 (Fed. Cir. 2016) (rejecting a claim of inventorship where plaintiff synthesized claimed superconducting compounds using methods which were ordinary skill in her profession); *Abbott Biotechnology*, 35 F. Supp. 3d at 171; *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 981 (Fed. Cir. 1997) (rejecting a claim of inventorship, describing the plaintiff’s contribution as explaining principles that “were well known and found in textbooks”).

Even assuming that Dr. Wang was the first one to tell Drs. Kimbrel and Lanza about the potential to use their MSCs in MS or EAE (*see* allegations at D.I. 20, at Countercl. ¶¶ 18-20, 32), that point is legally irrelevant. It does not change the fact that Dr. Wang contributed nothing beyond prior art knowledge, and thus he still cannot be an inventor. *See, e.g., Gen. Elec.*, 750 F.3d at 1332. Where the alleged co-inventor contributes “only well-known principles,” those

contributions “do not constitute the conception necessary to establish co-inventorship.” *Applied Elastomerics, Inc. v. Z-Man Fishing Prods., Inc.*, 521 F. Supp. 2d 1031, 1042 (N.D. Cal. 2007).

2. Merely performing tests to determine the effect of MSCs in the mouse EAE model is not sufficient to make Dr. Wang an inventor

Defendants ImStem and Dr. Wang also allege that Dr. Wang’s co-inventorship claim is supported by the EAE studies he performed using Drs. Kimbrel’s and Lanza’s MSCs, and the data he generated from those studies. But simply confirming operability of the MSCs by performing the EAE tests is insufficient to support a claim of co-inventorship, when the expected properties of MSCs and the EAE model were already known in the art. *See Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1230-31 (Fed. Cir. 1994).

“To be a joint inventor, an individual must make a contribution to the conception of the claimed invention.” *Caterpillar Inc.*, 387 F.3d at 1377 (alteration and citation omitted). Inventors need not personally conduct all of the steps necessary to reduce the invention to practice—“what matters for conception is whether the inventors had a definite and permanent idea of the operative inventions.” *Burroughs Wellcome*, 40 F.3d at 1230. Stated another way: “[t]he question is not whether [the inventors] reasonably believed that the inventions would work for their intended purpose . . . but whether the inventors had formed the idea of their use for that purpose in sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice.” *Id.* at 1231; *see also Stern v. Trustees of Columbia Univ.*, 434 F.3d 1375 (Fed. Cir. 2006) (conducting animal studies on the use of prostaglandins to treat glaucoma was insufficient for co-inventorship where individual had not collaborated on developing the treatment); *Intercept Pharm., Inc. v. Fiorucci*, --- F. Supp. 3d ----, 2017 WL 4314615, at *4 (D. Del. Sept. 28, 2017) (collaborator not a co-inventor where he performed testing that merely “amounted to screening and confirmation” that the inventor’s compound was effective).

The facts of *Burroughs Wellcome* bear strong similarity to the facts recited in Defendants' counterclaims. In *Burroughs Wellcome*, the Federal Circuit held that investigators who took compounds that had been developed by others and screened them for activity against HIV were not themselves inventors. The Burroughs Wellcome inventors developed a compound, AZT, with the intention of using it to treat HIV/AIDS. *Burroughs Wellcome*, 40 F.3d at 1230. The inventors collaborated with investigators at the National Institutes of Health ("NIH") to run confirmatory tests to demonstrate that compounds, including AZT, could inhibit HIV using a cell line developed by the NIH investigators. *Id.* The Federal Circuit agreed that, even though the NIH investigators exercised skill in testing and were some of the only individuals who could have done that screening test, they did not contribute anything to the invention of using AZT to treat AIDS. Instead, their testing merely confirmed the operability of the invention as conceived of by the Burroughs Wellcome inventors. *Id.*

So too here. According to Defendants' allegations, Dr. Wang took hemangioblast-derived MSCs from Dr. Kimbrel, tested those cells in the well-known EAE model, and provided the data from those tests that showed that these MSCs are therapeutically effective. (D.I. 20, at Ans. ¶ 35 (admitting that Defendants collected frozen MSCs for experiments), Countercl. ¶ 24 (Dr. Wang "conducted *in vivo* experiments on the EAE model . . . [and] sent the resulting data to Dr. Kimbrel.").)

Even taking Defendants' allegations as true, by the time Dr. Wang conducted the EAE tests, the inventors of the '956 patent had a definite idea of their invention, having already developed their method for making MSCs, and Dr. Wang simply confirmed their activity in a "commonly used" animal model. Consistent with this fact, the '956 patent includes data from other mouse models of diseases or disorders, including lupus, uveitis, and pain sensitivity. *See,*

e.g., '956 patent, 65:1-66:32, 66:45-47, 83:50-84:9; *id.* at Fig. 37A; (D.I. 1-4, at 15; *id.* at Fig. 6).

These models were similarly common and known in the art. *Id.*; *see also*, *e.g.*, '956 patent, 52:44-49, 66:45-49.

Dr. Wang's EAE tests merely confirmed and screened Drs. Kimbrel's and Lanza's hemangioblast-derived MSCs for therapeutic efficacy in the EAE model and in MS. What Dr. Wang contributed "was simply the normal course of . . . trials that mark the path of any [therapy] to the marketplace." *Burroughs Wellcome*, 40 F.3d at 1230. Drs. Kimbrel and Lanza did not have to know how to conduct the animal studies themselves to maintain their status as inventors. *See Tavory v. NTP, Inc.*, 297 F. App'x 976, 981 (Fed. Cir. 2008) (inventors are "not required to have known how to reduce their conceived inventions to practice to establish conception").

Thus, Dr. Wang's performance of the EAE studies⁸ using Drs. Kimbrel's and Lanza's MSCs does not qualify him as a co-inventor.

B. Dr. Wang's Contributions Were Insignificant When Measured Against The Whole Of The '956 Patent

Dr. Wang's purported contributions to the '956 patent constitute nothing more than suggesting, and testing, Drs. Kimbrel's and Lanza's MSCs in a known, prior art test. Thus, his claim to co-inventorship must fail. But in any event, his purported contributions are insignificant in the context of the '956 patent. *See Caterpillar*, 387 F.3d at 1377.

"[T]o be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." *Gipson v. Mattox*, 511 F. Supp. 2d 1182, 1188 (S.D. Ala.

⁸ Defendants may argue that Dr. Wang's co-authorship of the paper describing the EAE results from the collaboration with Drs. Kimbrel and Lanza (D.I. 1-2) demonstrates that he should be a co-inventor on the '956 patent. But that fact is insufficient to establish inventorship. *In re Katz*, 687 F.2d 450, 455 (Fed. Cir. 1982) (co-authors are not presumed to be co-inventors).

2007) (emphasis omitted) (quoting *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997)). Dr. Wang’s suggestion to treat autoimmune disease, and specifically MS, with Drs. Kimbrel’s and Lanza’s MSCs is “but a trifling component of the [’956 patent’s] invention.” *Id.* Drs. Kimbrel’s and Lanza’s claimed invention is that MSCs made through a hemangioblast intermediate can be used to treat over 60 diseases and disorders, only one of which is MS. ’956 patent, Claim 3.

The Notice of Allowance from the patent examiner who granted the patent cited the importance of the new method of making MSCs in the context of the claimed invention. *See* NOA at 2-3. Dr. Wang admits that he did not invent or even contribute to the method of deriving MSCs from hemangioblasts disclosed in the ’956 patent. (*See, e.g.*, D.I. 20, at Ans. ¶ 3 (admitting Drs. Kimbrel and Lanza developed the method for differentiating MSCs via hemangioblasts)). Contributing only one of a long list of diseases already known to be targets for MSC treatment, and nothing to the novel method of making MSCs at the core of the invention, Dr. Wang does not qualify to be named as an inventor. *See, e.g.*, *Gipson*, 511 F. Supp. 2d at 1188-89; *Irwin Indus. Tool Co. v. Bibow Indus., Inc.*, No. 11-30023-DPW, 2012 WL 5420033, at *4 (D. Mass. Nov. 6, 2012) (finding the contribution of the purported co-inventor “did not involve the core innovation” of the patent in suit); *Nartron Corp.*, 558 F.3d at 1358 (even contributing the sole limitation of one dependent claim was not significant in the context of the entire invention, where the alleged co-inventor did not contribute anything to the underlying independent claim).

C. Policy Considerations Support The Idea That Performance Of Routine Testing Is Insufficient For Inventorship

There are important policy considerations underpinning the holdings that a suggestion to use a known test to screen a compound or such confirmatory testing and screening is not

inventive. Inventors should not be required to build, for themselves, all the expertise necessary to develop, test, and confirm their inventions. Indeed, the Supreme Court recognized over 160 years ago that:

No invention can possibly be made, consisting of a combination of different elements . . . without a thorough knowledge of the properties of each of them, and the mode in which they operate on each other. And it can make no difference, in this respect, whether [the inventor] derives his information from books, or from conversation with men skilled in science. If it were otherwise, no patent, in which a combination of different elements is used, could ever be obtained.

O'Reilly, 56 U.S. (15 How.) at 111.

There are benefits to allowing inventors to rely on expertise in the field, instead of requiring them to reinvent all the wheels between conception of an invention and the marketplace. If individuals like Dr. Wang can claim co-inventorship merely by conducting routine testing, that would dissuade inventors from relying on collaborations to reduce their inventions to practice. That would in turn force inventors to, for example, conduct screening, animal, and clinical trials themselves when bringing a product to market. Otherwise, the inventors could risk losing ownership and control over the core of their inventions. The law does not require the inventor to build such expansive expertise: “an inventor does not lose his right to a patent merely by using the service, ideas and aid of others in the process of perfecting his invention.” *Applied Elastomerics, Inc.*, 521 F. Supp. 2d at 1042.

D. Plaintiffs’ Motion Is Not Premature

It is appropriate to dismiss ImStem and Dr. Wang’s inventorship counterclaim at the motion to dismiss stage. This is an unusual case where Dr. Wang’s pleading admits that he was not involved in the portion of the invention that led to the granting of a patent and further admits that the test he purportedly suggested was “commonly used.” These admissions are amply

supported by Dr. Wang's own writings, cited in the pleadings. Under the circumstances, the counterclaims cannot meet the necessary standard of providing plausible grounds for relief.

Twombly, 550 U.S. at 555; *see also Nisselson v. Lernout*, 469 F.3d 143, 154 (1st Cir. 2006) (it is appropriate to dismiss a claim under Rule 12(b)(6) where facts alleged in the complaint preclude a finding in the plaintiff's favor) (citations omitted).

This Court would not be the first to dismiss a claim for correction of inventorship under Federal Rule of Civil Procedure 12(b)(6). In *Coda Development*, the district court dismissed a cause of action seeking correction of inventorship on a Rule 12(b)(6) motion. 2016 WL 5463058, at *6. Like *Coda Development*, in this case the '956 patent "identifies [the] very concepts" Dr. Wang allegedly contributed as "prior art." *Id.* at *5; *supra* part IV.A. Likewise, Dr. Wang's own patent identifies those same concepts as prior art. *Coda Dev. s.r.o.*, 2016 WL 5463058, at *5 (noting that the plaintiffs' own patent applications disclosed the alleged contribution prior to the date of the patent in suit); *see supra* part IV.A (portions of the '551 patent confirm Dr. Wang's alleged contributions are prior art). The exact types of evidence Plaintiffs rely on here—patent specification, alleged co-inventor admissions, alleged co-inventor publications, and other prior art cited in the pleading—were considered by the *Coda Development* court in granting a motion to dismiss an inventorship counterclaim. *Coda Dev. s.r.o.*, 2016 WL 5463058, at *5-6; *see also, e.g., Peregrine Semiconductor Corp. v. RF Micro Devices, Inc.*, No. 3:12-CV-0911-H (WMC), 2014 WL 11997810, at *2-3 (S.D. Cal. Mar. 18, 2014).

Similarly, in *Arbitron, Inc. v. Kiefl*, No. 09-CV-04013 (PAC), 2010 WL 3239414 (S.D.N.Y. Aug. 13, 2010), the court weighed whether a purported co-inventor made a significant contribution to the conception of a patent at the motion to dismiss stage, concluded he did not,

and dismissed the suit. *Id.* at *6-7. There, the purported co-inventor alleged that he had contributed the use of cellular telephony as a means of data transfer, *id.* at *7, in the context of a patent directed to measuring the size of a radio audience by detecting a code conveying certain information that was embedded in the radio broadcasts, *id.* at *1. The court reasoned that the use of cellular telephony was “only one of many means of data transfer systems encompassed” by the patent and, as such, was not significant enough to prove co-inventorship. *Id.* at *7. The same analysis applies here, where, at best, Dr. Wang’s contribution relating to treating MS patients with hemangioblast-derived MSCs is merely “one of many” diseases the ’956 patent is directed to and MSCs had already been applied in MS disease models. *Supra* part IV.A.

E. The Unfair Competition Counterclaims Are Premised On Alleged Incorrect Inventorship, And Likewise Fail

Defendants’ unfair competition counterclaim is based on the same underlying facts as its correction of inventorship claim. Defendants specifically allege that “Plaintiffs have been unjustly enriched by the issuance of two valuable patents, both of which relied, in part, on the data that was generated exclusively by defendants.” (D.I. 20, at Countercl. ¶ 50.)

However, there is nothing unjust about the issuance of the ’956 and ’321 patents. A claim for unjust enrichment requires showing that that the accused party received a benefit, and that “benefit must be *unjust*.” *Glob. Inv’rs Agent Corp. v. Nat'l Fire Ins. Co.*, 927 N.E.2d 480, 494 (Mass. App. Ct. 2010) (emphasis in original). And there “was nothing improper or inherently unjust” in the identification of inventors on the ’956 and ’321 patents. *Max-Planck-Gesellschaft*, 850 F. Supp. 2d at 333. As above, Dr. Wang did not make any inventive contributions to the patented invention—the method of developing MSCs through a hemangioblast intermediate. *Supra* part IV.A-B. It was appropriate for the inventors to exclude Dr. Wang as a co-inventor. It is likewise appropriate to allow the inventors to retain the benefit

of their invention. In the absence of any inventive contributions on his part, Dr. Wang cannot reasonably expect to reap the benefits of others' inventive work. *See Shukh v. Seagate Tech., LLC*, No. 10-404 (JRT/JJK), 2011 WL 1258510, at *11 (D. Minn. Mar. 30, 2011).

V. CONCLUSION

For the foregoing reasons, Astellas requests that the Court dismiss ImStem and Xiaofang Wang's Counterclaims.

Dated: January 31, 2018

Respectfully submitted,

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